



# DEPARTMENT OF HEALTH AND HUMAN SERVICES

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## Centers for Medicare & Medicaid Services

[CMS-9086-N]

### Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—

April through June 2014

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice

**SUMMARY:** This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from April through June 2014, relating to the Medicare and Medicaid programs and other programs administered by CMS.

**FOR FURTHER INFORMATION CONTACT:** It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone Number
I CMS Manual Instructions	Ismael Torres	(410) 786-1864
II Regulation Documents Published in the <b>Federal Register</b>	Terri Plumb	(410) 786-4481
III CMS Rulings	Tiffany Lafferty	(410)786-7548
IV Medicare National Coverage Determinations	Wanda Belle	(410) 786-7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
VI Collections of Information	Mitch Bryman	(410) 786-5258
VII Medicare –Approved Carotid Stent Facilities	Lori Ashby	(410) 786-6322
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	Marie Casey, BSN, MPH	(410) 786-7861
IX Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin	(410) 786-7205
X One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin	(410) 786-7205
XI National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786-8564
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	Marie Casey, BSN, MPH	(410) 786-7861
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Marie Casey, BSN, MPH	(410) 786-7861
XIV Medicare-Approved Bariatric Surgery Facilities	Jamie Hermansen	(410) 786-2064
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	Stuart Caplan, RN, MAS	(410) 786-8564
All Other Information	Annette Brewer	(410) 786-6580

## I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance.

Administration and oversight of these programs involves the following: (1) furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining

effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

## **II. Format for the Quarterly Issuance Notices**

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This information is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and “real time” accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

### **III. How to Use the Notice**

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at <http://www.cms.gov/manuals>.

CMS-9086-N

Dated: July 18, 2014

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**Kathleen Cantwell**

Director,

Office of Strategic Operations and

Regulatory Affairs.

**BILLING CODE 4120-01-P**

### Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: July 26, 2013 (78 FR 45233), November 8, 2013 (78 FR 67153), January 31, 2014 (79 FR 5419), and April 25, 2014 (79 FR 22976). For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

### Addendum I: Medicare and Medicaid Manual Instructions (April through June 2014)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

#### How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: <http://cms.gov/manuals>.

#### How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400

designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at <http://www.gpo.gov/libraries/>

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) use CMS-Pub. 100-03, Transmittal No. 167.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual. For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at [www.cms.gov/Manuals](http://www.cms.gov/Manuals).

Transmittal Number	Manual/Subject/Publication Number
<b>Medicare General Information (CMS-Pub. 100-01)</b>	
85	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
86	Contractor Implementation of Change Requests and Compliance with Technical Direction Letters Sample Cover Letter/Attestation Statement CR Implementation Report (CRIR) Template TDL Compliance Report (TCR) Template
<b>Medicare Benefit Policy (CMS-Pub. 100-02)</b>	
187	Update to the Medicare Benefit Policy Manual to Restore Missing Air Ambulance Definitions Air Ambulance Services
188	Updates and Clarifications to the Hospice Policy Chapter of the Benefit Policy Manual Requirements - General Timing and Content of Certification Election, Revocation, and Change of Hospice

	Hospice Discharge Election by Managed Care Enrollees Drugs and Biologicals Coinsurance Respite Care Coinsurance Benefit Coverage Nursing Care Physicians' Services Nurse Practitioners as Attending Physicians Short-Term Inpatient Care Medical Appliances and Supplies Other Items and Services Continuous Home Care (CHC) Respite Care Other Issues Non-core Services Limitation on Liability for Certain Hospice Coverage Denials Documentation Limitations on Payments for Inpatient Care Counting Beneficiaries for Calculation Special Modalities
189	Invalidity of National Coverage Determination 140.3 - Transsexual Surgery Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare
<b>Medicare National Coverage Determination (CMS-Pub. 100-03)</b>	
166	Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors (This CR rescinds and fully replaces CR8468/TR2873 dated February 6, 2014) Positron Emission Tomography (FDG PET) for Oncologic Conditions
167	Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) Percutaneous image-guided lumbar decompression for lumbar spinal Stenosis
168	Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors (This CR rescinds and fully replaces CR8468/TR2873 dated February 6, 2014) Positron Emission Tomography (FDG PET) for Oncologic Conditions
169	Invalidity of National Coverage Determination 140.3 - Transsexual Surgery Transsexual Surgery
<b>Medicare Claims Processing (CMS-Pub. 100-04)</b>	
2918	Analysis and Implementation of Non-Medical Code Set Edit Bypass for Contractor Initiated Adjustment Claims in the Fiscal Intermediary Shared System (FISS)
2919	New Waived Tests
2920	Remittance Advice Remark and Claims Adjustment Reason Code and Medicare Remit Easy Print and PC Print Update
2921	Internet Only Manual Updates to Pub. 100-01, 100-02 and 100-04 to Correct Errors and Omissions

	Provider Charges to Beneficiaries Annual Updates to the SNF Pricer Other Excluded Services Beyond the Scope of a SNF Part A Benefit Other Services Excluded from SNF PPS and Consolidated Billing Ambulance Services Screening and Preventive Services Physician's Services and Other Professional Services Excluded From Part PPS Payment and the Consolidated Billing Requirement
2922	Medicare Claims Processing Pub. 100-04 Chapter 25 Update Uniform Bill - Form CMS-1450 Form Locators 43-81 Disposition of Copies of Completed Forms General Instructions for Completion of Form CMS-1450 for Billing Form Locators 1-15 Form Locators 31-41 Uniform Billing with Form CMS-1450
2923	April Update to the CY 2014 Medicare Physician Fee Schedule Database (MPFSDB)
2924	July 2013 Integrated Outpatient Code Editor (I/OCE) Specifications Version 14.2
2925	Corrections to the Medicare Claims Processing Manual Foreword Liability Considerations for Bundled Services CWF General Instruction Liability Considerations for Bundled Services Line-Item Modifiers Related to Reporting of Non-covered Charges When Covered and Non-covered Services Are on the Same Outpatient Claim Claims Processing Requirements for Financial Limitations Physician Fee Schedule Payment Policy Indicator File Record Layout General Billing Requirements Payment Coding That Results from Processing Noncovered Charges
2926	Chapter 29 Appeals Update (Includes Post-DOMA Guidance and Signature Requirement for Appointment of Representatives and Assignment of Appeal Rights) CMS Decisions Subject to the Administrative Appeals Process Who May Appeal Steps in the Appeals Process: Overview Where to Appeal Procedures to Follow When a Party Fails to Establish Good Cause Amount in Controversy General Requirements Principles for Determining Amount in Controversy Aggregation of Claims to Meet the Amount in Controversy Appointment of Representative - Introduction How to Make and Revoke an Appointment When and Where to Submit the Appointment Rights and Responsibilities of a Representative Duration of Appointment Curing a Defective Appointment of Representative How to Make and Revoke a Transfer of Appeal Rights

	<p>Curing a Defective Transfer of Appeal Rights</p> <p>Medicare Secondary Payer (MSP) Specific Limitations or Additional Requirements With Respect to the Appointment of Representatives Fraud and Abuse – Authority</p> <p>Appeals of Claims Involving Excluded Providers, Physicians, or Other Suppliers</p> <p>Required Elements in Appeals Correspondence</p> <p>General Information</p> <p>Appeal Decision Involving Multiple Beneficiaries</p> <p>Filing a Request for Redetermination</p> <p>The Redetermination</p> <p>The Redetermination Decision</p> <p>Dismissals</p> <p>Dismissal Letters</p> <p>Requests for U.S. District Court Review by a Party</p> <p>Medicare Redetermination Notice (For Partly or Fully Unfavorable Redeterminations)</p> <p>Medicare Redetermination Notice (For Fully Favorable Redeterminations)</p> <p>System and Processing requirements for Use of Secure Internet Portal/Application to Support Appeals Activities</p> <p>Reconsideration - The Second Level of Appeal</p> <p>Filing a Request for a Reconsideration</p> <p>Administrative Law Judge (ALJ) Hearing – The Third Level of Appeal</p> <p>Departmental Appeals Board – Appeals Council - The Fourth Level of Appeal</p> <p>District Court Review - The Fifth Level of Appeal</p> <p>Model Dismissal Notices</p>
2927	April 2014 Update of the Ambulatory Surgical Center (ASC) Payment System
2928	Enforcement of the 5 day Payment Limit for Respite Care Under the Hospice Medicare Benefit
2929	Update to Pub. 100-04, Medicare Claims Processing Manual, Chapter 11 to Provide Language-Only Changes for Updating ICD-10 and ASC X12 Requirement for RNHCI Election
2930	Update to Pub. 100-04, Medicare Claims Processing Manual, Chapter 11 to Provide Language-Only Changes for Updating ICD-10 and ASC X12
2931	<p>Aprepitant for Chemotherapy-Induced Emesis</p> <p>Billing and Payment Instructions for A/B MAC</p> <p>HCPCS Codes for Oral Anti-Emetic Drugs</p> <p>Claims Processing Jurisdiction for Oral Anti-Emetic Drugs</p> <p>Oral Anti-Emetic Drugs Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen</p>
2932	Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors (This CR rescinds and fully replaces CR8468/TR2873 dated February 6, 2014
2933	Addition of New Fields and Expansion of Existing Model 1 Discount Percentage Field in the Inpatient Hospital Provider Specific File (PSF) and Addition of New Fields and Renaming Payment Fields in the Inpatient Prospective Payment System (IPPS) Pricer Output
2934	April Update to the CY 2014 Medicare Physician Fee Schedule Database

	(MPFSDB)
2935	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2936	July 2014 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
2937	<p>Medicare Claims Processing Pub. 100-04 Chapter 31 Update</p> <p>Health Care Claim Status Category Codes and Health Care Claim Status Codes for Use with the Health Care Claim Status Request and Response</p> <p>ASC X12 276/277 Claim Status Request and Response</p> <p>Transmission Requirements</p> <p>Batch Transactions</p> <p>Online Direct Data Entry</p> <p>Interactive/Online (Non-DDE)</p> <p>Summary of the ASC X12 276/277 Claim Status Request and Response</p> <p>Process for A/B Medicare Administrative Contractors, DME MACs,</p> <p>CEDI</p> <p>Flat File</p> <p>Translation Requirements</p> <p>Transmission Mode</p> <p>Claim Status Request/Response Transaction Standard</p>
2938	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2939	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2940	Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - July 2014
2941	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2942	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2943	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2944	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2945	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2946	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2947	Medicare System Updates to Include Splints, Casts and Certain Intraocular Lenses Payment Category Indicators in the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule File and Alpha-Numeric HCPCS file
2948	Calendar Year (CY) 2014 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment - REVISION
2949	Adjustment to Fiscal Intermediary Shared System (FISS) Consistency Edit to Implement National Uniform Billing Committee (NUBC)

	Revision to Occurrence Span Code (OSC) Definition for Code 72.
2950	Adjustment to Fiscal Intermediary Shared System (FISS) Consistency Edit to Implement National Uniform Billing Committee (NUBC) Revision to Occurrence Span Code (OSC) Definition for Code 72.
2951	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2952	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2953	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2954	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2955	Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims General
2956	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2957	July 2014 Integrated Outpatient Code Editor (I/OCE) Specifications Version 15.2
2958	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2959	Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)
2960	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2961	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2962	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2963	Common Edits and Enhancements Modules (CEM) Code Set Update
2964	Indian Health Services (IHS) Hospital Payment Rates for Calendar Year 2014
2965	Medicare Claims Processing Pub. 100-04 Chapter 24 Update A - Response to a non - "unusual circumstance" waiver request Number of ASCS Enforcement Reviews to be Conducted by the RRB SMAC EDI Enrollment and EDI Claim Record Retention H - Notice from the Railroad Retirement Board Speciality MAC to a Provider with a Pre-Established Record in PES that Paper Claims Will be Denied as Result of the Requirements that a Provider Submit Claims to One or More Other Medicare Contractors Electronically B - Denial of an "unusual circumstance" waiver request C - Request for Documentation from Provider Selected for Review to Establish Entitlement to Submit Claims on Paper D - Notice that paper claims will be denied effective with the 91st calendar day after the original letter as result of non-response to that letter E - Notice that paper claims will be denied effective with the 91st calendar day after the original letter as result of determination that they provider is not eligible to submit paper claims

	F - Notice that determination reached that the provider is eligible to submit paper claims G - Notice from the Railroad Board Specialty Medicare Administrative Contractor (RRB SMAC) to a Provider that Has Just Begun to Submit Claims that Paper Claims Submitted by that Provider Will be Denied Network Service Vendor (NSV) Agreement
2966	Instructions for Downloading the Medicare ZIP Code File for October 2012
2967	Claim Status Category and Claim Status Codes Update
2968	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - October 2014
2969	Quarterly Update to the Correct Coding Initiative (CCI) Edits, Version 20.3, Effective October 1, 2014
2970	July 2014 Update of the Ambulatory Surgical Center (ASC) Payment System
2971	July 2014 Update of the Hospital Outpatient Prospective Payment System (OPPS) Type of Bill Method of Payment for Clinical Laboratory Tests - Place of Service Variation Hospital Billing Under Part B Critical Access Hospital (CAH) Outpatient Laboratory Service
2972	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
2973	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
2974	July Update to the CY 2014 Medicare Physician Fee Schedule Database (MPFSDB)
2975	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
2976	Changes to the Laboratory National Coverage Determination (NCD) Software
2977	Clarification of Billing Instructions Related to the Home Health Benefit Split Percentage Payment of Episodes Home health Consolidated Billing Edits in Medicare Systems More Than One Agency Furnished Home Health Services Grouper Links Assessment and Payment Submission of Request for Anticipated Payment (RAP) Claim Submission and Processing Payment, Claim Adjustments and Cancellations Adjustments of Episode Payment - Low Utilization Payment Adjustments (LUPAs) Adjustments of Episode Payment – Early or Later Episodes Adjustments of Episode Payment - Outlier Payments Glossary and Acronym List Home Health Prospective Payment System (HH PPS) Consolidated Billing General Guidelines for Processing Home Health Agency (HHA) Claims Therapy Editing Nonroutine Supply Editing Other Editing Related to Home Health Consolidated Billing Home Health Consolidated Billing and Supplies Provided by DMEPOS



	<p>Suppliers</p> <p>National Home Health Prospective Payment Episode History File</p> <p>Other Editing for HH PPS Episodes</p> <p>Coordination of HH PPS Claims Episodes With Inpatient Claim Types</p> <p>Request for Anticipated Payment (RAP)</p> <p>HH PPS Claims</p> <p>Collection of Deductible and Coinsurance from Patient</p> <p>Billing for Nonvisit Charges</p> <p>Beneficiary-Driven Demand Billing Under HH PPS</p> <p>No Payment Billing</p> <p>General</p> <p>Input/Output Record Layout</p> <p>Decision Logic Used by the Pricer on RAPs</p> <p>Decision Logic Used by the Pricer on Claims</p> <p>Medical and Other Health Services Not Covered Under the Plan of Care (Type of Bill 034x)</p> <p>Osteoporosis Injections as HHA Benefit</p> <p>Billing and Payment Procedures Regarding Ownership and CMS Certification Numbers (CCNs)</p> <p>Billing Procedures for an Agency Being Assigned Multiple CCNs or a Change in CCN</p> <p>Timeliness and Limitations of CWF Response</p>
2978	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
<b>Medicare Secondary Payer (CMS-Pub. 100-05)</b>	
101	<p>Additional Electronic Correspondence Referral System (ECRS) Reason Codes</p> <p>COBC Electronic Correspondence Referral System (ECRS)</p>
<b>Medicare Financial Management (CMS-Pub. 100-06)</b>	
236	<p>Revisions to Pub. 100-06, Section 100.2 – Amending Letter of Credit</p> <p>Amending Letters of Credit</p>
<b>Medicare State Operations Manual (CMS-Pub. 100-07)</b>	
115	New to State Operations Manual (SOM) Appendix Y- Organ Procurement Organization (OPO) Interpretive Guidance
116	<p>Revised State Operations Manual (SOM), Appendix A, Survey Protocol,</p> <p>Regulations and Interpretive Guidelines for Hospitals</p> <p>Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0957/§482.51(b)(4)/There must be adequate provisions for immediate post-operative care.</p> <p>Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0409/§482.23(c)(4)/Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures</p> <p>Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0412/§482.23(c)(6)/The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospitals defined and specified in the hospital's policies and procedures</p>

	Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0405/§482.23(c)Standard: Preparation and Administration of Drugs
117	<p>Revision to Medicare State Operations Manual (SOM), Chapter 9 – Exhibits</p> <p>37 Model Letter Announcing Validation Survey of Deemed Status Provider/Supplier</p> <p>162 Model Letter: Request for a Plan of Correction Following an Initial Survey for Swing-bed Approval in a Hospital</p> <p>196 Model Letter Announcing to Deemed Status Provider/Supplier after a Validation Survey that it does not Comply with all Medicare Conditions</p> <p>199 Model Letter Announcing to Deemed Status Provider/Supplier after a Substantial Allegation Survey that it will Undergo a Full Survey</p> <p>Authorization by Deemed Provider/Supplier Selected for Validation Survey</p> <p>Report of a Hospital Death Associated with Restraint or Seclusion (Form CMS-10455)</p>
118	<p>New Guidance Added to Chapter 7 – Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities</p> <p>Definitions and Acronyms</p> <p>Informal Dispute Resolution</p> <p>After Request to Waive Hearing</p> <p>Mandatory Elements of Informal Dispute Resolution</p> <p>Independent Informal Dispute Resolution (Independent IDR)</p> <p>Introduction</p> <p>Purpose</p> <p>Independent Informal Dispute Resolution Requirements</p> <p>Applicability of the Independent Informal Dispute Resolution Process</p> <p>Key Elements of Independent Informal Dispute Resolution</p> <p>Qualifications of an Independent Informal Dispute Resolution Entity or Person(s)</p> <p>Approval of an Independent Informal Dispute Resolution process</p> <p>State Budget and Payment for Expenses</p> <p>Independent Informal Dispute Resolution Recommendation and Final Decision</p> <p>Additional Elements for Federal Independent Informal Dispute Resolution process</p> <p>Notice Requirements</p> <p>When Immediate Jeopardy Exists</p> <p>Reduction of a Civil Money Penalty by 50 Percent for Self-Reporting and Prompt Correction of Noncompliance</p> <p>When Penalty Is Due and Payable</p> <p>When a Civil Money Penalty Subject to Being Collected and Placed in an Escrow Account is Imposed</p> <p>After Final Administrative Decision</p> <p>No Hearing Requested</p> <p>MODEL LETTER TO INVOLVED RESIDENT, RESIDENT REPRESENTATIVE AND/OR STATE OMBUDSMAN – OPPORTUNITY TO PROVIDE WRITTEN COMMENT (INDEPENDENT INFORMAL DISPUTE RESOLUTION (IDR) HAS BEEN REQUESTED)</p> <p>After Substantial Compliance is Achieved</p> <p>After Effective Date of Termination</p>

	Disposition of Collected Civil Money Penalty Collected From Medicare or Dually-Participating Facility Entities Other Than Nursing Homes May Receive Collected Civil Money Penalty Funds From the State Entities Other Than Nursing Homes May Receive Collected Civil Money Penalty Funds From the State Collected Amounts From Dually-Participating Facility or Medicare Facility and Held in Escrow Use of Civil Money Penalty Funds MODEL LETTER TO PROVIDER (SEND WITH FORM CMS-2567) (IMMEDIATE JEOPARDY DOES NOT EXIST) MODEL LETTER NOTIFYING PROVIDER OF RESULTS OF REVISIT MODEL LETTER TO PROVIDER (IMPOSITION OF REMEDIES) (IMMEDIATE JEOPARDY DOES NOT EXIST) MODEL LETTER TO PROVIDER (IMPOSITION OF REMEDIES) (IMMEDIATE JEOPARDY EXISTS) NOTICE OF IMPOSITION OF A CIVIL MONEY PENALTY (INSERT TO FORMAL NOTICE) NOTICE OF PAYMENT AMOUNT DUE AND PAYABLE NOTICE OF PAYMENT AMOUNT DUE FOR PLACEMENT IN ESCROW (IIDR COMPLETE OR NOT TIMELY REQUESTED-FACILITY IS FILING FORMAL APPEAL) Purpose - To Provide Facilities an Opportunity To Informally Dispute Cited Deficiencies After a Survey
<b>Medicare Program Integrity (CMS-Pub. 100-08)</b>	
510	Clarification to Pub. 100-02, Medicare Benefit Policy Manual Regarding Antigens and Deletion of Section 13.14 from Chapter 13 of Pub. 100-08, Medicare Program Integrity Manual Evaluation of Local Coverage Determination (LCD) Topics for National Coverage Determination (NCD) Consideration
511	Issued to a specific audience not posted to Internet/ Intranet due to Confidentiality of Instruction
512	Revision to the Program Integrity Manual, Chapter 3, section 3.3 <u>Policies and Guidelines Applied During Review</u>
513	Issued to a specific audience not posted to Internet/ Intranet due to Confidentiality of Instruction
514	Update to CMS Publication 100-08, Chapter 15 Potential Changes of Ownership Under the Principles of § 489.18 – Direct Referral to the Regional Office Required Radiation Therapy Centers Practice Location Information Form CMS-855A and Form CMS-855B Signatories Delegated Officials Submission of Registration Applications Registration Letters Certified Providers and Certified Suppliers Temporary Moratoria

	Model Approval Recommended Letters Initial Enrollments Requiring Referral to the State Initial Enrollments Requiring Direct Referral to the Regional Office (Including Federally Qualified Health Centers) Changes of Information Changes of Information Requiring Referral to the State Changes of Information Requiring Direct Referral to the Regional Office Potential Changes of Ownership Under the Principles of § 489.18 Potential Changes of Ownership Under the Principles of § 489.18 - Referral to the State Required Federally Qualified Health Centers (FQHCs)
515	Issued to a specific audience not posted to Internet/ Intranet due to Confidentiality of Instruction
516	Issued to a specific audience not posted to Internet/ Intranet due to Confidentiality of Instruction
517	Update to Surety Bond Collection Procedures Model Letters for Claims against Surety Bonds Claims against Surety Bonds
518	Issued to a specific audience not posted to Internet/ Intranet due to Confidentiality of Instruction \
519	Revision to CMS Publication 100-08, Chapter 15 Individual Practitioners Speech Language Pathologists in Private Practice Audiologists Certified Nurse-Midwives Certified Registered Nurse Anesthetists (CRNAs) Clinical Nurse Specialists Clinical Psychologists Clinical Social Workers Nurse Practitioners Occupational Therapists in Private Prac Physical Therapists in Private Practice Physicians Physician Assistants (PAs) Psychologists Practicing Independently Registered Dietitians Anesthesiology Assistants
520	Issued to a specific audience not posted to Internet/ Intranet due to Confidentiality of Instruction
521	Submission of Community Mental Health Center (CMHC) Certifications of Compliance with Section 485.918(b)(1) Release of Information CMHC 40 Percent Rule Section 4 of the Form CMS-855I Special Procedures for Physicians and Non-Physician Practitioners Community Mental Health Centers (CMHCs)
522	Issued to a specific audience not posted to Internet/ Intranet due to Confidentiality of Instruction
523	Update to CMS Pub. 100-08, Chapter 3 Reimbursing Providers and HIHs for Additional Documentation

524	Issued to a specific audience not posted to Internet/ Intranet due to Confidentiality of Instruction
525	Update to Form CMS-855 Application Processing Sections of CMS Pub. 100-08, Chapter 15 Sections of the Forms CMS-855A, CMS-855B, and CMS-855I Medicare Contractor Duties Changes of Information and Complete Form CMS-855 Applications Correspondence Address and E-mail Addresses Contact Persons Application Review and Verification Activities Receipt/Review of Application and Verification of Data Receipt/Review of Paper Applications Receipt/Review of Internet-Based PECOS Applications Verification of Data Requesting Missing/Clarifying Data/Documentation Paper Applications Internet-Based PECOS Applications General Principles – Paper and Internet-Based PECOS Applications Receiving Missing/Clarifying Data/Documentation Failure to Submit Requested Data/Documentation Paper Applications Internet-Based PECOS Applications Reserved for Future Use Reserved for Future Use Requesting and Receiving Clarifying Information Basic Information (Section 1 of the Form CMS-855)
526	Issued to a specific audience not posted to Internet/ Intranet due to Confidentiality of Instruction
527	Provider Notice on MAC Web Sites Provider Notice
528	Proof of Delivery Supplier Documentation
<b>Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)</b>	
28	Revision of Pub. 100-09, Chapter 6, Medicare Contractor Beneficiary and Provider Communications Manual; Clearance of MAC Internet-Based Provider Portal Handbook; and Deletion of IOM Pub. 100-09, Chapter 3, Provider Inquiries. Introduction to Provider Customer Service Program (PCSP) PCSP Electronic Mailing Lists (Listservs) Provider Customer Service Program User Group (PCUG) Calls PCSP Contractor Sharing and Collaboration Team Room Integration of POE, PCC and PSS Activities in the PCSP Provider Outreach and Education (POE) Internal Development of Provider Issues Partnering with External Entities Data Analysis Error Rate Reduction Data Inquiry Analysis Medical Review Referrals Provider Education

Provider Bulletins/Newsletters Direct Mailings for the PCSP Training for New Medicare Providers Training Tailored for Small Medicare Providers Educational Topics Local Coverage Determinations (LCDs) Education Resulting from Medical Review Referrals Medicare Preventive Service Benefits Electronic Claims Submissions Remittance Advice (RA) POE Materials POE Advisory Groups (POE AGs) Ask-the-Contractor" Teleconferences (ACTs) POE Reporting Provider Service Plan (PSP) Provider Customer Service Program Activity Report (PAR) Error Rate Reduction Plan (ERRP) Additional Reporting charging Fees to Providers for Medicare Education and Training No Charge Fair and Reasonable Fees Fees for Materials Available on Contractors' Provider Education Websites Fees for Education and Training Activities Fees for Videotapes or Recordings of Education and Training Activities Prohibitions Reimbursement from Providers for POE Staff Attendance at Provider Meetings Excess Revenues from Provider Participant Fees Refunds/Credits for Cancellation of Education and Training Activities Considerations and Recordkeeping for Fee Collection Provider Contact Center (PCC) Inquiry Triage Process Responding to Coding Questions Provider Telephone Inquiries General Inquiries Line Teletypewriter (TTY) Lines Inbound Calls Troubleshooting Problems Requesting Changes to Telephone Configurations Hours of Operation PCC Closures Pre-Approved PCC Closures Planned PCC Closures that are not Pre-Approved Closures Emergency PCC Closures Providing Busy Signals Queue Message PCC Staffing CSR Equipment Requirements CSR Identification to Callers Remote Monitoring Access
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	Contingency Plans Guidelines for High Quality Responses to Telephone Inquiries Telephone Response Quality Monitoring Program Telephone Responses -- Quality Call Monitoring (QCM) Program Minimum Requirements Recording Calls QCM Calibration CMS Monitoring Provider Written Inquiries Controlling Written Inquiries Telephone Responses to Written Inquiries E-mail and Fax Responses to Written Inquiries Guidelines for High Quality Responses to Written Inquiries Stock Language/Form Letters Written Response Quality Monitoring Program Written Responses -- Quality Written Correspondence Monitoring (QWCM) Program Minimum Requirements QWCM Calibration Replying to Correspondence from Members of Congress Walk-In Inquiries Guidelines for Walk-In Service Complex Provider Inquiries Complex Beneficiary Inquiries Inquiry Tracking Updates for the CMS Standardized Provider Inquiry Chart Fraud and Abuse Surveys Provider Satisfaction Survey Telephone Satisfaction Survey Provider Education Website Satisfaction Survey PCSP Staff Development and Education POE Staff Training PCC Staff Development and Training Required Training PCC Training Program Training Schedule Training Closures of More Than Four Hours Provider Notifications Training Closure Information Reporting PRRS Staff Training Provider Self-Service (PSS) Technology Interactive Voice Response System (IVR) Provider Education Website General Requirements Webmaster and Attestation Requirements Feedback Mechanism Contents Dissemination of Information from CMS to Providers Frequently Asked Questions (FAQs) Quarterly Provider Update (QPU)
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	Internet-based Provider Educational Offerings Provider Education Website Promotion Electronic Mailing List (Listserv) Targeted Electronic Mailing Lists (Listservs) Electronic Mailing List (Listserv) Promotion Social Media Contractor Internet-based Provider Portals PCSP Performance Management POE - Electronic Mailing List (Listserv) Subscribership Telephone Standards Customer Service Representative (CSR) Callback Rate Call Completion Average Speed of Answer (ASA) Callbacks QCM Performance Standards Written Inquiries QWCM Performance Standards General Inquiries Timeliness PRRS Timeliness - Provider Inquiries PRRS Timeliness -- Complex Beneficiary Inquiries Congressional Inquiries Timeliness PCSP Data Reporting Provider Inquiries Evaluation System (PIES) Access to PIES Due Date for Data Submission Data to be Reported Monthly Provider Customer Service Program Contractor Information Database (PCID) Access to PCID Contract Data to be Reported in PCID Other Data to be Reported in PCID Inquiry Tracking Data to be Reported in PCID Disclosure of Information POE Data to be Reported in PCID Provider Electronic Mailing List (Listserv) Subscriber Data to be Reported in PCID Special Initiatives to be Reported in PCID Emergency PCC Closure Data to Be Reported in PCID Telecommunications Service Interruptions to be Reported in PCID QCM Data Reporting QWCM Data Reporting Reporting Provider and Beneficiary Inquiry Workload Data in the Contractor Reporting of Operational Workload Data (CROWD) PCC Training Closure Information to be Reported in PCID
29	Revision of Pub. 100-09, Chapter 6, Medicare Contractor Beneficiary and Provider Inquiries. Introduction to Provider Customer Service Program (PCSP) PCSP Electronic Mailing Lists (Listservs) Provider Customer Service Program User Group (PCUG) Calls PCSP Contractor Sharing and Collaboration Team Room

	<p>Integration of POE, PCC and PSS Activities in the PCSP</p> <p>Provider Outreach and Education (POE)</p> <p>Internal Development of Provider Issues</p> <p>Partnering with External Entities</p> <p>Data Analysis</p> <p>Error Rate Reduction Data</p> <p>Inquiry Analysis</p> <p>Medical Review Referrals</p> <p>Provider Education</p> <p>Provider Bulletins/Newsletters</p> <p>Direct Mailings for the PCSP</p> <p>Training for New Medicare Providers</p> <p>Training Tailored for Small Medicare Providers</p> <p>Educational Topics</p> <p>Local Coverage Determinations (LCDs)</p> <p>Education Resulting from Medical Review Referrals</p> <p>Medicare Preventive Service Benefits</p> <p>Electronic Claims Submissions</p> <p>Remittance Advice (RA)</p> <p>POE Materials</p> <p>POE Advisory Groups (POE AGs)</p> <p>Ask-the-Contractor" Teleconferences (ACTs)</p> <p>POE Reporting</p> <p>Provider Service Plan (PSP)</p> <p>Provider Customer Service Program Activity Report (PAR)</p> <p>Error Rate Reduction Plan (ERRP)</p> <p>Additional Reporting</p> <p>charging Fees to Providers for Medicare Education and Training</p> <p>No Charge</p> <p>Fair and Reasonable Fees</p> <p>Fees for Materials Available on Contractors' Provider Education Websites</p> <p>Fees for Education and Training Activities</p> <p>Fees for Videotapes or Recordings of Education and Training Activities</p> <p>Prohibitions</p> <p>Reimbursement from Providers for POE Staff Attendance at Provider Meetings</p> <p>Excess Revenues from Provider Participant Fees</p> <p>Refunds/Credits for Cancellation of Education and Training Activities</p> <p>Considerations and Recordkeeping for Fee Collection</p> <p>Provider Contact Center (PCC)</p> <p>Inquiry Triage Process</p> <p>Responding to Coding Questions</p> <p>Provider Telephone Inquiries</p> <p>General Inquiries Line</p> <p>Teletypewriter (TTY) Lines</p> <p>Inbound Calls</p> <p>Troubleshooting Problems</p> <p>Requesting Changes to Telephone Configurations</p> <p>Hours of Operation</p> <p>PCC Closures</p>
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	<p>Pre-Approved PCC Closures</p> <p>Planned PCC Closures that are not Pre-Approved Closures</p> <p>Emergency PCC Closures</p> <p>Providing Busy Signals</p> <p>Queue Message</p> <p>PCC Staffing</p> <p>CSR Equipment Requirements</p> <p>CSR Identification to Callers</p> <p>Remote Monitoring Access</p> <p>Contingency Plans</p> <p>Guidelines for High Quality Responses to Telephone Inquiries</p> <p>Telephone Response Quality Monitoring Program</p> <p>Telephone Responses -- Quality Call Monitoring (QCM) Program Minimum Requirements</p> <p>Recording Calls</p> <p>QCM Calibration</p> <p>CMS Monitoring</p> <p>Provider Written Inquiries</p> <p>Controlling Written Inquiries</p> <p>Telephone Responses to Written Inquiries</p> <p>E-mail and Fax Responses to Written Inquiries</p> <p>Guidelines for High Quality Responses to Written Inquiries</p> <p>Stock Language/Form Letters</p> <p>Written Response Quality Monitoring Program</p> <p>Written Responses -- Quality Written Correspondence Monitoring (QWCM)</p> <p>Program Minimum Requirements</p> <p>QWCM Calibration</p> <p>Replying to Correspondence from Members of Congress</p> <p>Walk-In Inquiries</p> <p>Guidelines for Walk-In Service</p> <p>Complex Provider Inquiries</p> <p>Complex Beneficiary Inquiries</p> <p>Inquiry Tracking</p> <p>Updates for the CMS Standardized Provider Inquiry Chart</p> <p>Fraud and Abuse</p> <p>Surveys</p> <p>Provider Satisfaction Survey</p> <p>Telephone Satisfaction Survey</p> <p>Provider Education Website Satisfaction Survey</p> <p>PCSP Staff Development and Education</p> <p>POE Staff Training</p> <p>PCC Staff Development and Training</p> <p>Required Training</p> <p>PCC Training Program</p> <p>Training Schedule</p> <p>Training Closures of More Than Four Hours</p> <p>Provider Notifications</p> <p>Training Closure Information Reporting</p> <p>PRRS Staff Training</p> <p>Provider Self-Service (PSS) Technology</p>
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	Interactive Voice Response System (IVR) Provider Education Website General Requirements Webmaster and Attestation Requirements Feedback Mechanism Contents Dissemination of Information from CMS to Providers Frequently Asked Questions (FAQs) Quarterly Provider Update (QPU) Internet-based Provider Educational Offerings Provider Education Website Promotion Electronic Mailing List (Listserv) Targeted Electronic Mailing Lists (Listservs) Electronic Mailing List (Listserv) Promotion Social Media Contractor Internet-based Provider Portals PCSP Performance Management POE - Electronic Mailing List (Listserv) Subscribership Telephone Standards Customer Service Representative (CSR) Callback Rate Call Completion Average Speed of Answer (ASA) Callbacks QCM Performance Standards Written Inquiries QWCM Performance Standards General Inquiries Timeliness PRRS Timeliness - Provider Inquiries PRRS Timeliness -- Complex Beneficiary Inquiries Congressional Inquiries Timeliness PCSP Data Reporting Provider Inquiries Evaluation System (PIES) Access to PIES Due Date for Data Submission Data to be Reported Monthly Provider Customer Service Program Contractor Information Database (PCID) Access to PCID Contract Data to be Reported in PCID Other Data to be Reported in PCID Inquiry Tracking Data to be Reported in PCID Disclosure of Information POE Data to be Reported in PCID Provider Electronic Mailing List (Listserv) Subscriber Data to be Reported in PCID Special Initiatives to be Reported in PCID Emergency PCC Closure Data to Be Reported in PCID Telecommunications Service Interruptions to be Reported in PCID QCM Data Reporting QWCM Data Reporting Reporting Provider and Beneficiary Inquiry Workload Data in the Contractor
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	Reporting of Operational Workload Data (CROWD) PCC Training Closure Information to be Reported in PCID
<b>Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)</b>	
00	None
<b>Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)</b>	
2	Issued to a specific audience not posted to Internet/ Intranet due to Confidentiality of Instruction
<b>Medicare Managed Care (CMS-Pub. 100-16)</b>	
00	None
<b>Medicare Business Partners Systems Security (CMS-Pub. 100-17)</b>	
00	None
<b>Demonstrations (CMS-Pub. 100-19)</b>	
98	Affordable Care Act Bundled Payments for Care Improvement Initiative - Recurring File Updates Models 2 and 4 July 2014 Updates
99	Issued to a specific audience not posted to Internet/ Intranet due to Sensitivity of Instruction
100	Issued to a specific audience not posted to Internet/ Intranet due to Sensitivity of Instruction
101	Correction to CR 8599- Implementation of the Intravenous Immune Globulin (IVIG) demonstration
102	Issued to a specific audience not posted to Internet/ Intranet due to Sensitivity of Instruction
103	Issued to a specific audience not posted to Internet/ Intranet due to Confidentiality of Instruction
104	Implementing Payment Changes for FCHIP (Frontier Community Health Integration Project), Mandated by section 123 of MIPPA 2008 and as amended by section 3126 of the ACA of 2010
105	Affordable Care Act Bundled Payments for Care Improvement Initiative – Recurring File Updates Models 2 and 4 October 2014 Updates
<b>One Time Notification (CMS-Pub. 100-20)</b>	
1365	Reporting principal and interest amounts when refunding previously recouped money on the Remittance Advice (RA)
1366	Termination of the Common Working File ELGA, ELGH, HIQA, HIQH, and HUQA Part A Provider Queries
1367	Implementation of NACHA Operating Rules for Health Care Electronic Funds Transfers (EFT)
1368	International Classification of Diseases, 10th Revision (ICD-10) Testing with Providers through the Common Edits and Enhancements Module (CEM) and Common Electronic Data Interchange (CEDI) - Additional Testing Week
1369	Clarification of Remittance Advice Code Combination Reports Generated by Shared Systems
1370	Implement Operating Rules - Phase III ERA EFT: CORE 360 Uniform Use of Claim Adjustment Reason Codes (CARC) and Remittance Advice Remark Codes (RARC) Rule - Update from CAQH CORE - February 1, 2014 version 3.0.4
1371	Instructions to Contractors for Implementing Section 5506 of the Affordable Care Act (ACA) - Preservation of Resident Cap Positions from Closed Teaching Hospitals – Rounds 1, 2, 3 and After
1372	Affordable Care Act (ACA) Bundled Payments for Care Improvement –

	Periodic Financial Transactions
1373	CWF Editing for Vaccines Furnished at Hospice – Correction
1374	Health Insurance Portability and Accountability Act (HIPAA) EDI Front End Updates for October 2014
1375	Adding New MSP Data Fields to the CWF Daily File
1376	Return Maintenance of the ANSILIST to the Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs).
1377	Hewlett Packard Enterprise Services, LLC (HPES) Shared Systems Maintainer (SSM) support for Medicare Administrator Contractors (MACs) testing and inquiries for the Combined Common Edits/Enhancements Module (CCEM) for Part A and Part B
1378	Implement Operating Rules - Phase III ERA EFT: CORE 360 Uniform Use of Claim Adjustment Reason Codes (CARC) and Remittance Advice Remark Codes (RARC) Rule - Update from CAQH CORE - June 1, 2014 version 3.0.5
1379	Anesthesiologist/Certified Registered Nurse Anesthetist (CRNA) Related Services in a Method II Critical Access Hospital (CAH)
1380	Present on Admission (POA) Indicator Editing for Maryland Waiver Hospitals
1381	CEM Zip Code Analysis and Design
1382	Analysis and Design of the ASC X12 278 Transactions
1383	Implementation of a Prospective Payment System (PPS) for Federally Qualified Health Centers (FQHCs)
1384	Posting the Limiting Charge after Applying the Electronic Health Record (EHR) and Physician Quality Reporting System (PQRS) Negative Adjustments
1385	Additional States Requiring Payment Edits for DMEPOS Suppliers of Prosthetics and Certain Custom-Fabricated Orthotics. Update to CR 3959 and CR 8390
1386	Modifying the Daily Common Working File (CWF) to Medicare Beneficiary Database (MBD) File to Include Diagnosis Codes on the Health Insurance Portability and Accountability Act Eligibility Transaction System (HETS) 270/271 Transactions
1387	Clarification of Remittance Advice Code Combination Reports Generated by Shared Systems
1388	ICD-10 Conversion/Coding Infrastructure Revisions/ICD-9 Updates to National Coverage Determinations (NCDs)--Maintenance CR
1389	CWF, MCS and VMS Date of Birth (DOB) Analysis

### **Addendum II: Regulation Documents Published in the Federal Register (April through June 2014)**

#### Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register**, contact GPO at [www.gpo.gov/fdsys](http://www.gpo.gov/fdsys). When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at <http://www.gpoaccess.gov/fr/index.html>. The following website <http://www.archives.gov/federal-register/> provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our website at: <http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-2Q14QPU.pdf>

For questions or additional information, contact Terri Plumb (410-786-4481).

### **Addendum III: CMS Rulings**

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings>. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

### **Addendum IV: Medicare National Coverage Determinations (April through June 2014)**

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also

been posted on the CMS website. For the purposes of this quarterly notice, we list only the specific updates that have occurred in the 3-month period. This information is available at: [www.cms.gov/medicare-coverage-database/](http://www.cms.gov/medicare-coverage-database/). For questions or additional information, contact Wanda Belle (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis	NCD150.13	R167	05/16/2014	01/09/2013
ICD-10 Conversion/Coding Infrastructure Revisions/ICD-9 Updates to National Coverage Determinations (NCDs)	N/A	R133	05/23/2014	07/01/2014

#### Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (April through June 2014)

Addendum V includes listings of the FDA-approved investigational device exemption (IDE) numbers that the FDA assigns. The listings are organized according to the categories to which the devices are assigned (that is, Category A or Category B), and identified by the IDE number. For the purposes of this quarterly notice, we list only the specific updates to the Category B IDEs as of the ending date of the period covered by this notice and a contact person for questions or additional information. For questions or additional information, contact John Manlove (410-786-6877).

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c) devices fall into one of three classes. To assist CMS under this categorization process, the FDA assigns one of two categories to each FDA-approved investigational device exemption (IDE). Category A refers to experimental IDEs, and Category B refers to non-experimental IDEs. To obtain more information about the classes or categories, please refer to the notice published in the April 21, 1997 **Federal Register** (62 FR 19328).

IDE	Device	Start Date
G140034	ROCHE COBAS EGFR MUTATION TEST	04/03/2014
BB15945	ReCell Autologous Cell Harvesting Device (ReCell)	04/03/2014
G140035	Strattice Reconstructive Tissue Matrix	04/04/2014
G140039	EVERA MRI SURESCAN ICD SYSTEM CLINICAL STUDY	04/09/2014
G130185	BARREL VASCULAR RECONSTRUCTION DEVICE	04/10/2014
BB15963	Dermagraft, Human Fibroblast-Derived Dermal Replacement	04/11/2014

G140054	Medtronic Specify 5-6-5 / Medtronic Restore Advance	04/11/2014
G140040	Blanketrol III	04/17/2014
G130286	WEB Aneurysm Embolization System	04/17/2014
G130072	Ovinium DH Hip System	04/22/2014
G140043	Transcaval Access For Transcatheter Aortic Valve Replacement in Patients With No Good Options For Aortic Access	04/23/2014
G140046	PerMIT: Warfarin	04/23/2014
BB15998	Magnetic-Activated Cell Sorter (CliniMACS, Miltenyi) for CD34 Selection, Allogeneic, Matched-related PBPC	04/24/2014
G140048	Inferior Vena Cava Filters	04/25/2014
G140049	EON Implantable Pulse Generator (IPG) System (Model 3688), Libra Implantable Deep Brain Stimulation (DBS) Electrodes (Model 6145), Swift-Lock Anchor (Model 1192)	04/25/2014
G140050	Mi1000 Med-EL Concert Cochlear Implant	04/25/2014
BB15978	Nstride APS Kit	04/27/2014
BB15983	Magnetic Activated Cell Sorter (CliniMACS, Miltenyi) for CD34+ Selected Allogeneic Mismatched/Haplocompatible Related, G-CSF Mobilized Hematopoietic Stem Cells(HSCs); following Fludarabine and rATG, with or without Radiation	04/30/2014
G140056	Model 400 Aortic Valve Bioprosthesis	05/01/2014
G140058	Therascreen BRAF V600E RGQ PCR Kit	05/01/2014
G140059	Corevalve Evolut R System	05/02/2014
G140060	Gore Tag Thoracic Branch Endoprosthesis	05/02/2014
G140065	VENTANA anti-ALK (D5F3) Rabbit Monoclonal Primary Antibody	05/07/2014
G130264	Hot Axios Stent And Delivery System (With 10mm x 10mm Stent) HXS-10-10, Hot Axios Stent And Delivery System (With 15mm x 10mm Stent) HXS-15-10	05/08/2014
G140024	Saluda Medical External Trial System	05/16/2014
G140018	Saluda Medical External Trial System	05/16/2014
G140077	Liposorber LA-40S Adsorption Column	05/22/2014
G140083	Zeltiq Coolsculpting System	05/30/2014
G140080	XpreESS Multi-Sinus Dilation Tool, PathAssist LED Light Fiber, PathAssist Light Fiber, PathAssist Light Seeker	05/30/2014
G140087	Sinopsys Lacrimal Stent	06/03/2014
G140084	Pipeline Embolization Device Model FA-772XX-XX-FA-775XX-XX, Pipeline Embolization Device Model FA-712XX-XX-FA-715XX-XX	06/04/2014
G140082	ExAblate 4000 Typer 1.0 Transcranial magnetic resonance image	06/04/2014
G140091	Bead/Bead Block Compressible Microspheres (BeadBlock)	06/13/2014
G140092	Cardiac Resynchronization Therapy Efficacy Enhancements (CRTee) Clinical Study	06/13/2014
G140027	Transarterial embolization to avoid open prostatectomy in patients with severe benign prostatic hyperplasia (Embosphere Microspheres)	06/13/2014
G130256	SCULPTRA-2013-01	06/20/2014
G140093	Custom-Made, Non-Biodegradable, Antibiotic Cement Spacer	06/26/2014
G140099	VenaCure EVLT 400um Procedure Kit	06/27/2014



**Addendum VI: Approval Numbers for Collections of Information  
(April through June 2014)**

All approval numbers are available to the public at [Reginfo.gov](http://Reginfo.gov). Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). For questions or additional information, contact Mitch Bryman (410-786-5258).

**Addendum VII: Medicare-Approved Carotid Stent Facilities,  
(April through June 2014)**

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: <http://www.cms.gov/MedicareApprovedFacilities/CASF/list.asp#TopOfPage>. For questions or additional information, contact Lori Ashby (410-786-6322).

Facility	Provider Number	Effective Date	State
<b>The following facility is a new listing for this quarter.</b>			
Penrose-St. Francis Health Services 2222 N. Nevada Avenue Colorado Springs, CO 80907	060031	04/24/2014	CO
The Heart Hospital Baylor Denton 2809 S. Mayhill Road Denton, TX 76208	1194753590	06/02/2014	TX

**Addendum VIII:  
American College of Cardiology's National Cardiovascular Data  
Registry Sites (April through June 2014)**

Addendum VIII includes a list of the American College of Cardiology's National Cardiovascular Data Registry Sites. We cover implantable cardioverter defibrillators (ICDs) for certain clinical indications, as long as information about the procedures is reported to a central registry. Detailed descriptions of the covered indications are available in the NCD. In January 2005, CMS established the ICD Abstraction Tool through the Quality Network Exchange (QNet) as a temporary data collection mechanism. On October 27, 2005, CMS announced that the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) ICD Registry satisfies the data reporting requirements in the NCD. Hospitals needed to transition to the ACC-NCDR ICD Registry by April 2006.

Effective January 27, 2005, to obtain reimbursement, Medicare NCD policy requires that providers implanting ICDs for primary prevention clinical indications (that is, patients without a history of cardiac arrest or spontaneous arrhythmia) report data on each primary prevention ICD procedure. Details of the clinical indications that are covered by Medicare and their respective data reporting requirements are available in the Medicare NCD Manual, which is on the CMS website at <http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961>.

A provider can use either of two mechanisms to satisfy the data reporting requirement. Patients may be enrolled either in an Investigational Device Exemption trial studying ICDs as identified by the FDA or in the ACC-NCDR ICD registry. Therefore, for a beneficiary to receive a Medicare-covered ICD implantation for primary prevention, the beneficiary must receive the scan in a facility that participates in the ACC-NCDR ICD registry. The entire list of facilities that participate in the ACC-NCDR ICD registry can be found at [www.ncdr.com/webncdr/common](http://www.ncdr.com/webncdr/common).

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available by accessing our website and clicking on the link for the American College of Cardiology's National Cardiovascular Data Registry at: [www.ncdr.com/webncdr/common](http://www.ncdr.com/webncdr/common). For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

Facility	City	State
<b>The following facilities are new listings for this quarter.</b>		
Houston Medical Center	Warner Robins	GA
Tahlequah City Hospital	Tahlequah	OK
South County Hospital	Walefield	RI
Wolfson Children's Hospital	Jacksonville	FL
West Park Hospital	Cody	WY
MaryVale Hospital	Phoenix	AZ
Parkland Medical Center	Derry	NH
Sentara Northern Virginia Medical Center	Woodbridge	VA
Lovelace Regional Hospital	Roswell	NM
Wheaton Franciscan ? Elmbrook Memorial Campus	Brookfield	WI
Kaiser Foundation Hospital	Fontana	CA
Prairie Ridge Hospital and Health Services	Elbow Lake	MN
Hanover Hospital	Hanover	PA
St. Barnabas Hospital	Bronx	NY
Wellington Regional Medical Center	Wellington	FL
Carilion New River Valley Medical Center	Christiansburg	VA
<b>The following facilities are terminated as of this quarter.</b>		
Summit Medical Center (6/16/14)	Van Buren	AR
Yakima Valley Memorial Hospital (6/30/14)	Yakima	WA

#### **Addendum IX: Active CMS Coverage-Related Guidance Documents (April through June 2014)**

There were no CMS coverage-related guidance documents published in the April through June 2014 quarter. To obtain the document, visit the CMS coverage website at <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=23>. For questions or additional information, contact JoAnna Baldwin (410-786-7205).

#### **Addendum X:**

##### **List of Special One-Time Notices Regarding National Coverage Provisions (April through June 2014)**

There were no special one-time notices regarding national coverage provisions published in the April through June 2014 quarter. This information is available at [www.cms.hhs.gov/coverage](http://www.cms.hhs.gov/coverage). For questions or additional information, contact JoAnna Baldwin (410 786 7205).

#### **Addendum XI: National Oncologic PET Registry (NOPR) (April through June 2014)**

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission

tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the April through June 2014 quarter. This information is available at <http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage>. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

#### **Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (April through June 2014)**

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred to the list of Medicare-approved facilities that meet our standards in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage>. For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

Facility	Provider Number	Date Approved	State
<b>The following facilities are new listings for this quarter.</b>			
New York-Presbyterian/Weill Cornell Medical Center 525 East 68th Street New York, NY 10065	33-0101	08/22/2013	NY

**Addendum XIII: Lung Volume Reduction Surgery (LVRS)  
(April through June 2014)**

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. There were no updates to the listing of facilities for lung volume reduction surgery published in the April through June 2014 quarter. This information is available at [www.cms.gov/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage). For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

**Addendum XIV: Medicare-Approved Bariatric Surgery Facilities  
(April through June 2014)**

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1)

certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS's minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the April through June 2014 period. This information is available at [www.cms.gov/MedicareApprovedFacilities/BSF/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilities/BSF/list.asp#TopOfPage). For questions or additional information, contact Jamie Hermansen (410-786-2064).

**Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (April through June 2014)**

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the April through June 2014 quarter.

This information is available on our website at [www.cms.gov/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage). For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

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